(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /___/

If yes, explain: _____

_____

_____ 4/9/97

Signature Date

Title: Project Manager

_____ 6/19/98

Signature of [redacted] Date

Division Director

cc: Original NDA Division File HFD-85 Mary Ann Holovac

DRUG STUDIES IN PEDIATRIC PATIENTS
(To be completed for all NME's recommended for approval)

NDA # 20-521 Trade (generic) names INFASURF (calfactant)

Check any of the following that apply and explain, as necessary, on the next page:

✓ 1. A proposed claim in the draft labeling is directed toward a specific pediatric illness. The application contains adequate and well-controlled studies in pediatric patients to support that claim.

___ 2. The draft labeling includes pediatric dosing information that is not based on adequate and well-controlled studies in children. The application contains a request under 21 CFR 210.58 or 314.126(c) for waiver of the requirement at 21 CFR 201.57(f) for A&WC studies in children.

___ a. The application contains data showing that the course of the disease and the effects of the drug are sufficiently similar in adults and children to permit extrapolation of the data from adults to children. The waiver request should be granted and a statement to that effect is included in the action letter.

___ b. The information included in the application does not adequately support the waiver request. The request should not be granted and a statement to that effect is included in the action letter. (Complete #3 or #4 below as appropriate.)

___ 3. Pediatric studies (e.g., dose-finding, pharmacokinetic, adverse reaction, adequate and well-controlled for safety and efficacy) should be done after approval. The drug product has some potential for use in children, but there is no reason to expect early widespread pediatric use (because, for example, alternative drugs are available or the condition is uncommon in children).

___ a. The applicant has committed to doing such studies as will be required.

___ (1) Studies are ongoing.
___ (2) Protocols have been submitted and approved.
___ (3) Protocols have been submitted and are under review.
___ (4) If no protocol has been submitted, on the next page explain the status of discussions.

___ b. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

___ 4. Pediatric studies do not need to be encouraged because the drug product has little potential for use in children.

____ 5. If none of the above apply, explain.

Explain, as necessary, the foregoing items: INFASURF is only indicated for infants with Respiratory Distress Syndrome (RDS).

Signature of Preparer

3/4/96
Date

cc: Orig NDA
HFD-___/Div File
NDA Action Package

FAX: (212) 750-9152
DIRECT LINE:

DEBARMENT CERTIFICATION

In compliance with Section 306(k) of the Federal Food, Drug and Cosmetic Act, we hereby certify that Forest Laboratories, Inc. did not and will not use in any capacity the services of any person debarred under sub section 306(a) or (b) of the Act in connection with this application (NDA #20-521) for Infasurf® (Calf Lung Surfactant Extract) Intratracheal Suspension.

FOREST LABORATORIES, INC.

Michael M. Rosen, Ph.D.
Director of Regulatory Affairs

ONY INC
BAIRD RESEARCH PARK
1576 SWEET HOME ROAD • AMHERST, NEW YORK 14228
(716) 636-9096 (800) 274-4669

DEBARMENT CERTIFICATION

In compliance with Section 306(k) of the Federal Food, Drug and Cosmetic Act, we hereby certify that Ony, Inc. did not and will not use in any capacity the services of any person debarred under sub section 306(a) or (b) of the Act in connection with this application (NDA #20-521) for Infasurf® (Calf Lung Surfactant Extract) Intratracheal Suspension.

Edmund A. Egan, M.D.
President

JUL 12 1996

MEMORANDUM

DATE: July 12, 1996

TO: NDA 20-521

FROM: John K. Jenkins, M.D
Director, Division of Pulmonary Drug Products HFD-570

7/12/96

SUBJECT: Overview of NDA Review Issues

Administrative

NDA 20-521 for Infasurf (calf lung surfactant extract, CLSE) was originally submitted by ONY (in partnership with Forest Laboratories) on March 13, 1995. Following extensive internal discussions regarding the issue of Orphan Drug Exclusivity protection for Survanta and the similarity/differences between Infasurf and Survanta, the Division refused the file the application in a letter dated May 10, 1995 based on the fact that Infasurf and Survanta were deemed to be the "same" drug for the purposes of Orphan Drug Exclusivity and there were no data in the original application to demonstrate clinical superiority of Infasurf over Survanta. The Division met with the sponsor on July 6, 1995 to review the reasons for the RTF decision. At that meeting the sponsor presented a scientific argument and some preliminary data which suggested that Infasurf and Survanta were not the "same" drug; the argument was primarily based on the sponsor's assertion that Infasurf contained substantially more surfactant associated protein B (SP-B) than Survanta and that the levels of SP-B in Survanta were so low as to be inactive. Following internal discussions of the new information presented by the sponsor at the meeting of July 6, 1995, the Division notified ONY in a letter dated July 13, 1995 that the application would be refiled provided; 1) the data supporting the contribution of SP-B to the effect of Infasurf was included in the resubmitted NDA, and 2) the sponsor commit to providing comparative CMC data from an FDA inspected laboratory for the analysis of SP-B in both Infasurf and Survanta within 4 months of resubmission of the NDA. The NDA was resubmitted on July 31, 1995 with the above data/commitments as well as a comparative clinical trial of Infasurf versus Survanta for the prophylaxis and treatment of RDS. The resubmitted application was filed by the Division. An IR letter listing CMC deficiencies was issued on February 28, 1996 and a meeting with the sponsor to discuss the issues contained in this letter was held on March 20, 1996. The sponsor was informed by teleconference on April 26, 1996 and by letter on May 24, 1996 that the Center had determined that Infasurf and Survanta were considered to be the "same" drug for the purposes of Orphan Drug Exclusivity and that Infasurf could not be approved until the 7 year Orphan Drug Exclusivity for Survanta expires in July 1998. The sponsor was also informed that if they should desire to attempt to demonstrate that Infasurf was in fact "different" from Survanta for the purposes of Orphan Drug Exclusivity based on an "active moiety" concept for a particular component of the surfactants that they would be required to "demonstrate both that the particular component is present and active in one surfactant and that it is either not present or present at levels that are inactive in the other surfactant". Another meeting with the sponsor to discuss several of the

CMC issues contained in the February 28, 1996 CMC IR letter was held on July 9, 1996. The current User Fee Goal Date for NDA 20-521 is July 31, 1996.

Clinical

The proposed indication for Infasurf is for "the prevention of Respiratory Distress Syndrome (RDS) in premature infants and the treatment ("rescue") of newborn infants who develop RDS. Infasurf significantly decreases the incidence of RDS, the severity of RDS, mortality due to RDS, and air leaks associated with RDS." In support of this indication, the sponsor submitted three multicenter, randomized, masked, active-controlled, trials of Infasurf versus either Exosurf or Survanta for the prophylaxis or treatment of RDS (Study SCT-P vs Exosurf for prophylaxis of RDS, Study SCT-T vs Exosurf for the treatment of RDS, and ISCT-92 versus Survanta for the prophylaxis and treatment of RDS). Studies SCT-P and SCT-T are considered the pivotal demonstrations of efficacy; Study ISCT-92 is considered supportive. Please see the integrated Clinical/Statistical Review by Drs. Pina and Koutsoukos for more complete details on the design/results of these studies. A brief overview of each of these studies will be presented here.

Efficacy:

Study SCT-P: This trial compared Infasurf (3 ml/kg Q12 hrs for up to 3 doses) and Exosurf (5 ml/kg Q12 hrs for up to 3 doses) for the prevention of RDS in 871 premature babies ≤28 weeks gestation and ≤1100 grams body weight. For the primary endpoints in the intent-to-treat population, Infasurf was statistically significantly more effective than Exosurf in decreasing the incidence of RDS and mortality secondary to RDS and not significantly different (and essentially numerically the same) for the incidence of BPD. For the secondary endpoints in the intent-to-treat population, Infasurf was generally equal to, or numerically better than Exosurf for all endpoints and statistically significantly better than Exosurf for some endpoints (e.g., total respiratory mortality, incidence of crossover surfactant treatment).

Study SCT-T: This study compared Infasurf (3 ml/kg, two doses Q12 hrs) and Exosurf (5 ml/kg, two doses Q12 hrs) for the treatment of RDS in 1,133 premature infants with established RDS. For the primary endpoints in the intent-to-treat population, Infasurf was statistically significantly more effective than Exosurf in reducing the incidence of RDS related air leaks (the original protocol defined primary endpoint) but was not statistically significantly different from Exosurf for the severity of RDS over the first 24 hours, the incidence of BPD, or mortality secondary to RDS (for each of these three "primary" endpoints Infasurf was numerically the same or slightly better than Exosurf). For the secondary endpoints in the intent-to-treat population, Infasurf was numerically better, though not statistically different from Exosurf, on total respiratory mortality, neonatal mortality, incidence of crossover surfactant treatment, incidence of acute pulmonary hemorrhage, and severity of BPD.

Study ISCT-92: This study compared Infasurf (4 ml/kg of 25 mg phospholipids/ml suspension [proposed marketed formulation is 35 mg/ml], up to four doses) and Survanta (4 mg/kg, up to 4 doses) for the prevention of RDS in 463 premature infants ≤30 weeks gestation and ≤1250 grams body weight and for the treatment of RDS in 662 premature infants with established RDS. Prophylaxis: For the intent to treat population (Note: the primary endpoint(s) were not

prospectively identified, retrospectively intact cardiopulmonary survival was defined as the primary endpoint; the power calculations for the study were reported to have been based on detection of a 15% net reduction in the Survanta rate of babies requiring two doses of drug), there was a trend favoring Survanta for intact CP survival at 28 days ($p=0.08$), there were statistically significantly fewer total deaths ($p=0.03$) and respiratory deaths ($p=0.005$) in the Survanta group (no difference in non-respiratory deaths), there was no difference in the incidence of BPD at 28 days, there was no difference in the incidence of RDS or the severity of RDS, and there was no difference in the incidence of pulmonary complications of RDS (i.e., PTX, PIE, any air leak). There were statistically significant differences in the hours between dose 2 to dose 3 and dose 3 to dose 4 in favor of Infasurf (mean difference between groups of 5-7 hours). Treatment: For the intent to treat population (see note above regarding primary endpoint designation, the power calculations for the study were reported to have been based on detection of an 18% net reduction in the Survanta rate of babies requiring three doses of drug), there was no difference in the incidence of intact CP survival at 28 days, there was no difference for any mortality parameter, there was no difference in incidence of BPD at 28 days, there were statistically significant differences in RDS severity at 24 hours in favor of Infasurf, and there was no difference in pulmonary complications of RDS. As observed in the prophylaxis trial, there were statistically significant differences in the hours between dose 1 to dose 2, dose 2 to dose 3, and dose 3 to dose 4 in favor of Infasurf (mean difference between groups of 3-4 hours). In addition, statistically significantly fewer babies in the Infasurf group required 4 or more doses of drug compared to Survanta. The were also small, but statistically significant differences in the level of FiO_2 support and mean airway pressure (MAP) in favor of Infasurf during the first 48 hours of treatment. Overall, the results of the prophylaxis and treatment components of this trial do not clearly demonstrate that Infasurf is clinically superior to Exosurf with regard to efficacy outcomes. While Infasurf did have a longer dosing interval than Survanta in both arms of the trial and significantly reduced the number of babies requiring 4 or more doses as well as FiO_2 and MAP in the treatment arm, these differences were small and of questionable clinical significance given the lack of correction of these results for multiple statistical comparisons and the observed statistically significant decreased mortality in the Survanta arm of the prophylaxis trial. At best, this trial is supportive of the efficacy of Infasurf in the prophylaxis and treatment of RDS given the fact that for many of the endpoints for which Survanta has been demonstrated in placebo controlled trials to be effective Infasurf was numerically similar to Survanta.

Safety:
Study SCT-P: For the intent to treat population, there was a statistically significant greater incidence of periventricular leukomalacia (PVL) and intraventricular hemorrhage (IVH) in the Infasurf group when analyzed as the combination of PVL and IVH or when analyzed as PVL or IVH or both. When analyzed based on patient outcome (i.e., 'died or survived with PVL and/or severe IVH' or 'survived without PVL or severe IVH) there were no statistically significant differences between the treatment groups, however, very small numerical trends favored a better outcome with Exosurf. For complications of prematurity (e.g., retinopathy of prematurity, patent ductus arteriosis, apnea, necrotizing entercolitis, sepsis) no differences were observed between the treatment groups. There were also statistically significant greater incidences of adverse events associated with the administration of the study drug (bradycardia,

airway obstruction, cyanosis, manual ventilation) in the Infasurf group.

Study SCT-T: For the intent to treat population, there was a statistically significant lesser incidence of IVH in the Infasurf group, however, when analyzed as the incidence of PVL and IVH there was a statistically significant greater incidence in the Infasurf group. When analyzed based on patient outcome (see above) no differences were seen between the treatment groups. For complications of prematurity, no differences were observed between the treatment groups. As in the Exosurf prophylaxis trial, there were statistically significant greater incidences of adverse events associated with the administration of the study drug (bradycardia, airway obstruction, cyanosis, manual ventilation) in the Infasurf group.

ISCT-92: Prophylaxis No statistically significant differences were observed for PVL, IVH, and other complications of prematurity, however, with regard to PVL and IVH there were small numerical trends in favor of lower incidence and better patient outcomes with Survanta. There were statistically significant greater incidences of adverse events associated with the administration of study drug (airway obstruction, requirement for suctioning within one hour of dosing) in the Infasurf group. Treatment There was a statistically significant greater incidence of mild IVH in the Survanta group and numerically more patients with severe IVH in the Infasurf arm. As in each of the other studies, there were statistically significant greater incidences (or strong trends) of adverse events associated with the administration of the study drug (airway obstruction, requirement for suctioning within one hour $p=0.07$).

Summary:
The two pivotal trials which compared Infasurf to Exosurf adequately support the efficacy of Infasurf for the prevention and treatment of RDS in premature infants. The trial which compared Infasurf to Survanta failed to demonstrate that Infasurf is clinically superior to Survanta; the findings of an increased dosing interval and decreased FiO_2 and MAP in the Infasurf group were of questionable clinical significance and insufficient to explain away the statistically significant decreased mortality in the Survanta treated group in the prophylaxis trial. From a safety perspective, the major concerns are the apparent increased incidence of intraventricular hemorrhage and adverse events associated with administration of the drug seen in the Infasurf group when compared to both Exosurf and Survanta. It is uncertain how this finding may be linked to the use of Infasurf and when the data are analyzed on the basis of patient outcome no statistically significant differences were seen. The clinical significance of these findings, therefore, remain unclear and should not preclude approval of Infasurf with appropriate labeling. The adverse events associated with administration of the drug were clearly more frequent with Infasurf than Exosurf (although Infasurf was more effective) and somewhat more frequent than with Survanta. These adverse events were generally transient and not severe and should not preclude the approval of Infasurf with appropriate labeling for adverse events and administration precautions.

Infasurf is considered clinically approvable for the prevention and treatment of RDS in premature infants with appropriate labeling to detail the findings of the pivotal clinical trials summarized above.

Preclinical

Please see the preclinical review by Dr. Choi for a more detailed assessment of the preclinical studies submitted by the sponsor. With regard to toxicology, the sponsor submitted an acute intratracheal toxicity study in newborn rabbits and a 7 day intratracheal toxicity study in newborn pigs. There was little toxicity of Infasurf in these studies with the exception of clinical findings associated with the actual administration of the drug. Infasurf was not mutagenic in the Ames test. No carcinogenicity or chronic toxicology studies were conducted, or required, for this application due to the limited duration of dosing proposed for labeling. The sponsor only submitted one multi-dose toxicology study to the NDA which does not meet the usual requirement of two species. This issue was dealt with by the Division in the past and the decision was made to not require the second species given the extensive clinical data available for the product.

Infasurf is considered approvable from a preclinical standpoint with appropriate labeling to reflect the available preclinical database.

CMC

Please see the CMC review by Dr. Nashed for more complete details of the CMC review of Infasurf.

As noted in the Administrative section of this memo, the sponsor has been informed that the Center has determined that naturally derived surfactants are the "same" drug for the purposes of Orphan Drug Exclusivity. In the meeting of July 6, 1996 the sponsor argued that Infasurf is not the "same" drug as Survanta and primarily based on their argument on their contention that the levels of SP-B in Infasurf are much higher than those in Survanta and that the SP-B levels in Infasurf are critical to its activity while the levels of SP-B in Survanta are not active. The sponsor was requested to submit data and methods for assay of SP-B in Infasurf and Survanta and informed that a regulatory specification would be required for this claimed active ingredient. Subsequently, in the letter dated May 24, 1996, the sponsor was informed that if they choose to challenge the Agency's determination that Infasurf and Survanta are the "same" drug based on the "active moiety" concept that they would need to "demonstrate both that the particular component is present and active in one surfactant and that it is either not present or present at levels that are inactive in the other surfactant". The sponsor has submitted data and methods for the assay of SP-B in Infasurf and Survanta and this has been reviewed by Dr. Nashed (see CMC deficiencies in the action letter).

Infasurf is considered not-approvable from a CMC standpoint and the outstanding deficiencies will be included in the action letter to the sponsor.

Biopharmaceutics

The sponsor requested a waiver of the requirement for submitting evidence of in-vivo bioavailability (21 CFR 320.22(e)) of Infasurf and Dr. Gillespie has recommended that that request be granted.

Infasurf is considered approvable from a biopharmaceutics standpoint and a waiver of the requirement for submitting evidence of in-vivo bioavailability should be granted.

Data Verification

The Division of Scientific Investigations (DSI) completed audits at a total of 6 clinical sites from the pivotal efficacy trials (SCT-P, SCT-T). Five of the sites were reported as VAI and one site was reported as NAI. The audit reports were reviewed by Dr. Pina who noted that at 3 of the 6 sites patients were reported by the investigator to have air leaks on their CXR, however, these findings were not reported by the sponsor in the NDA. This finding is particularly important (despite the fact that based on the data Dr. Pina reviewed it appears that the failure to report the air leaks resulted in Infasurf actually looking worse on this endpoint) since the incidence of air leaks was the primary endpoint for SCT-T and an important secondary endpoint in SCT-P. These findings bring into question the integrity of the NDA database and the sponsor will be asked in the action letter to explain how these discrepancies occurred and to provide a detailed report of the auditing procedures that were conducted by the sponsor in putting together the NDA to insure that this is not a systematic problem.

Labeling

The proposed trade name, Infasurf, is acceptable to the Division and was reviewed and found

acceptable by the Labeling and Nomenclature Committee. The remainder of the labeling has not been reviewed at this point since the NDA is not being approved at this point and the outstanding deficiencies and Orphan Drug Exclusivity issues will preclude approval in the near future. A comment will be added to the action letter that labeling comments will be provided once the application is closer to being approved.

Microbiology

Per the review by Dr. Vincent the sponsor has submitted adequate data to assure sterility of the drug product provided the sponsor commit to additional controls which will be communicated to the sponsor in the action letter.

Conclusion

The primary outstanding issues for this NDA are the CMC deficiencies and the issue of the findings from the DSI audit and the question of the overall integrity of the database. From a clinical standpoint the sponsor has provided adequate data to support the safety and efficacy of Infasurf (assuming the integrity of the database is assured), therefore, in accord with current Center policy on the issuance of action letters, this application is APPROVABLE. Deficiencies from the various disciplines will be communicated to the sponsor in the action letter.

cc:
NDA 20-521
HFD-570 Division Files
HFD-570/Jenkins
HFD-570/Schumaker
HFD-570/Kuzmik
HFD-570/Himmel
HFD-570/Pina

KUZMIK

AUG 28 1995

INFASURF®
Intratracheal Suspension
(Calf Lung Surfactant Extract)

NDA 20-521

Ony, Incorporated
Amherst, NY

Type of Submission:
NDA
NME
Submission Dates:
March 13, 1995
Reviewer:
Brad Gillespie, PharmD
Purpose:
Suitability for Filing

BACKGROUND INFASURF is intended to be used intratracheally for the prevention and treatment of Respiratory Distress Syndrome (RDS) in premature neonates. Clinical data has been submitted for two parallel, active controlled trials comparing INFASURF to EXOSURF NEONATAL®. Safety of the product has been demonstrated in open clinical trials involving in excess of 14,000 patients.

PHARMACOKINETICS Conventional bioavailability/pharmacokinetic studies were not performed with INFASURF. The sponsor provides the following rationale for this omission:

1) The drug is administered and acts locally (luminal surface of the alveolar epithelium). Systemic absorption is minimal.

2) The target population is so medically fragile, that such studies would carry high risks of acute and long term morbidity. The sponsor specifically notes that:
- Premature and newborn infants are not acceptable candidates for radiolabel studies
- Drawing excessive blood in these patients with minimal blood volumes is an unacceptable risk
- Installation of liquid into the lungs of an infant after the onset of breathing without a specific therapeutic intent carries a significant risk of severe vagal cardiopulmonary responses or interruption of ventilation

Thus, the sponsor requests a waiver of the requirement for evidence of in vivo bioavailability under 21 CFR 320.22 (e).

DISCUSSION Two neonatal pulmonary surfactants have received FDA approval for marketing: EXOSURF® (Colfosceril, Burroughs Wellcome Company), a totally synthetic, protein-free product approved in August, 1990. And SURVANTA® (Beractant, Ross Laboratories), a bovine extract approved in July, 1991. Neither sponsor was required to

perform human bioavailability/pharmacokinetic studies (see Dr Pradheep Sathe's Biopharmaceutics review of the colfosceril bio-waiver request of October, 1990).

CFR 320.22 (e) states that FDA may for good cause waive a requirement for the submission of evidence of in vivo bioavailability if that waiver is compatible with the protection of the public health.

CONCLUSION The product described in this submission appears to fit the criteria used to waive human bioavailability requirements in earlier pulmonary surfactant submissions.

RECOMMENDATION On its face, this submission appears fileable from a Biopharmaceutics perspective.

8/28/95

Bradley K. Gillespie, PharmD
Pharmacokinetics Evaluation Branch

FT 8/28/95
Mehul U. Mehta, PhD, Section Head (Acting)

cc:
HFD-150 (NDA-20-521)
HFD-150 (Division File)
HFD-150 (Pina)
HFD-151 (Kuzmik)
HFD-426 (Mehta)
HFD-426 (Fleischer)
HFD-427 (Chen, Mei Ling)
HFD-426 (Chron)
HFD-426 (Gillespie, Brad)
HFD-340 (Viswanthan)
HFD-019 (FOI)

USAN

UNITED STATES ADOPTED NAMES COUNCIL

RUTA FREIMANIS, Pharm.D., R.Ph., Secretary
(312) 464-4045

American Medical Association
515 North State Street
Chicago, Illinois 60610

Telefax: 312-464-4184

April 21, 1997

JJ-18

ONY, Inc.
Baird Research Park
1576 Sweet Home Road
Amherst, NY 14228

Attn.: Edmund A. Egan, MD
President/Chief Medical Officer

Dear Dr. Egan:

The USAN Council has completed its evaluation of your September 3, 1996, request for a nonproprietary name for Ony's calf lung lavage extract trademarked Infasurf and being developed for the prevention and treatment of neonatal respiratory distress syndrome (RDS).

Your suggested names, (1) calf lung surfactant extract and (2) CLSE were rejected by the Council because they are not constructed in accordance with the USAN Nomenclature rules as published in the USP Dictionary of USAN and International Drug Names. In place of your suggested terms, the USAN Council selected and recommends adoption of **calfactant.** Please evaluate this counterproposal. If it is acceptable to Ony, we shall forward the name and pertinent background information to the WHO International Name Committee for nonproprietary name and trademark clearance. Please note that the WHO Committee currently is not assigning names to natural mixtures of this type and will not be formally selecting an International Nonproprietary Name for Infasurf.

The WHO review process will require approximately eight to twelve weeks. At the end of this time and in the absence of any reported nomenclature problems, calfactant will be adopted as the USAN for your substance.

I look forward to acceptance of the name by Ony. Do not hesitate to contact me if you have any questions.

Sincerely yours,

Ruta Freimanis

Ruta Freimanis, PharmD
Secretary, USAN Council

RF/dmk

ONY INC
BAIRD RESEARCH PARK
1576 SWEET HOME ROAD • AMHERST, NEW YORK 14228
(716) 636-9096 (800) 274-4669

April 25, 1997

Ruth Freimanis, PharmD
Secretary, USAN Council
United States Adopted Names Council
American Medical Association
515 North State Street
Chicago, Ill 60610

Dear Secretary Freimanis,

ONY, Inc accepts the non-proprietary name of calfactant for its calf lung lavage extract trademarked as Infasurf you recommended in your April 21, 1997 letter.

Thank you for your assistance.

Sincerely,

Edmund A. Egan, MD
President

EAE/USAN1.047

REQUEST FOR TRADEMARK REVIEW

To: Labeling and Nomenclature Committee

Attention: Dan Boring, Chair (HFD-530), 9201 Corporate Blvd, Room N461

From: Division of Pulmonary Drug Products	**HFD- 570**
Attention: Mr. Dan Boring	**Phone:** 827-2333
Date: May 9, 1996	
Subject: Request for Assessment of a Trademark for a Proposed New Drug Product	
Proposed Trademark: Infasurf	**NDA# 20-521**
Established name, including dosage form: None available, suspension	
Other trademarks by the same firm for companion products: NA	
Indications for Use (may be a summary if proposed statement is lengthy): Prevention and Treatment of respiratory distress syndrome (RDS) in premature infants and treatment ("rescue") of newborn infants who develop RDS.	
Initial Comments from the submitter (concerns, observations, etc.): A similar bovine-derived surfactant product, trade name Survanta, has an established name of beractant.	